REMARKS

Reconsideration of the present application, as amended, is respectfully requested.

The April 25, 2002 Office Action and the Examiner's comments have been carefully considered. In response, claims are amended and added, the specification and Abstract are amended, and remarks are set forth below in a sincere effort to place the present application in form for allowance. The amendments are supported by the application as originally filed. Therefore, no new matter is added.

SPECIFICATION AND ABSTRACT

The specification is amended to add section headings and to correct typographical, grammatical and/or translation errors of which applicants have become aware.

The Abstract is amended to eliminate reference numerals and to place the Abstract in better form. No new matter is added.

Entry of the amendments to the specification and Abstract are respectfully requested.

REJECTION UNDER 35 USC 112

In the Office Action claims 3 and 6 are rejected under the second paragraph of 35 USC 112 as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicants regard as the invention. Specifically, the Examiner questions the meaning of the term "projection line". In response, applicants respectfully state that the term "projection line" is clear in its usage in the claims, and even further the term is explained in the specification at page 9, line 28 - page 10, line 25, inter alia. "Projection line" corresponds to lines which are perpendicular to the spinal axis line 21. The projection line is generated such that there is no overlap with parts of the anatomy for the portion of the anatomy (e.g., vertebrae of interest) of the patient so that a clear image of the area of interest is provided.

Since the term "projection line" is clear from its usage in the claims and is clearly explained in the specification, reconsideration and withdrawal of the rejection of claims 3 and 6 under the second paragraph of 35 USC 112 are respectfully requested.

PRIOR ART REJECTIONS

In the Office Action claims 1, 2, 7 and 9 are rejected under 35 USC 102(b) as being anticipated by USP 5,369,678 (Chiu). Claims 1-9 are rejected under 35 USC 103 as being unpatentable over USP 5,365,562 (Toker).

In response, claims 1 and 9 are amended to more clearly define over the cited references. Claims 1 and 9, and 2-8 are amended to be in better form for consideration by the Examiner.

The present claimed invention as defined by claim 1 is directed to a method for imaging anatomical parts of the human anatomy by means of an X-ray apparatus. The method includes the steps of acquiring at least one initial projection image of at least the region of interest of the human anatomy, determining the positions and/or orientations of the plurality of anatomical parts in the region of interest from the at least one initial projection image and/or from other sources of information, determining optimum imaging parameters for each of the plurality of anatomical parts from their positions and/or orientations (e.g., each vertebrae of the spine), and acquiring images of the anatomical parts while using respective optimum imaging parameters for each of the plurality of anatomical parts.

The present claimed invention as defined by claim 9 is directed to an X-ray apparatus for imaging a plurality of anatomical parts of the human anatomy, in particular parts of the human spine, having an X-ray source and an X-ray detector facing the X-ray source. The X-ray source and the X-ray detector are movable with respect to each other and with respect to the patient so as to enable the acquisition of projection images of each of the plurality of anatomical parts from different positions and/or orientations. The X-ray apparatus includes a control unit for controlling the X-ray apparatus such that at least one initial projection image of at least the region of interest of the human anatomy is acquired, and a processing unit for determining the position and/or orientation of anatomical parts in the region of interest from the at least one initial projection image and/or from other sources of information. method also includes determining optimum imaging parameters for the anatomical parts from their positions and/or orientations. The optimum imaging parameters are used by the control unit to control the X-ray apparatus such that images of each of the anatomical parts using the optimum parameters are acquired.

Chiu et al teach a method for tracking a catheter probe 18

during a fluoroscopic procedure. Chiu et al teach utilizing an apparatus (collimator assembly 20 which includes a filter plate 22) to reduce the X-ray dosage provided to the patient by confining the full X-ray dosage to a central area of interest 30 which corresponds to the location of the catheter tip. Chiu et al describe how to compensate for the reduced X-ray dosage in the areas 32, 34 which are peripheral to the central area 30 which receives the full X-ray dosage by computer imaging enhancement. Chiu et al teach that the area of interest in this application is a tip of the catheter which is preferably positioned in the unattenuated center region of the collimator which corresponds to the center region 30 of the viewed image.

In contrast to Chiu et al which tracks a catheter probe, the present claimed invention as defined by claim 1 is directed to a method for imaging anatomical parts of the human body. While Chiu et al acquire a projection image (which may correspond to the at least one initial projection image of the claimed invention) Chiu et al do not determine the positions and/or orientations of the plurality of anatomical parts in the region of interest based on the initial projection image (Chiu only determines a location of a catheter tip which is not an

anatomical part), nor does Chiu et al determine optimum imaging parameters for each of the plurality of anatomical parts of interest from their positions and/or orientations within the acquired image. Moreover, Chiu et al do not acquire images of the plurality of anatomical parts while using respective optimum imaging parameters for each of the plurality of anatomical parts.

Moreover, it would not have been obvious to one of ordinary skill in the art at the time the invention was made to modify the disclosure of Chiu et al to arrive at the present claimed invention as defined by claim 1.

In view of the foregoing, claim 1, and claims 2 and 7 which are dependent thereon, are patentable over Chiu et al under 35 USC 102 as well as 35 USC 103.

Independent claim 9 is patentable over Chiu et al for reasons, inter alia, set forth above in connection with claim 1. Specifically, Chiu et al do not disclose, teach or suggest an X-ray apparatus which includes a processing unit for determining the position and/or orientation of anatomical parts in a region of interest of the human body from the at least one initial projection image, nor does it disclose determining optimum imaging parameters for each of the plurality of anatomical parts

based on their positions and/or orientations identified by the initial projection image.

Moreover, it would not have been obvious to one of ordinary skill in the art at the time the invention was made to modify the disclosure of Chiu et al to arrive at the present claimed invention as defined by claim 9.

In view of the foregoing, claim 9 is patentable over Chiu et al under 35 USC 102 as well as 35 USC 103.

Toker discloses a medical imaging system which is adaptable to suit specific imaging conditions. Toker teaches employing a variety of medical or non-medical image settings wherein desired image contrast and resolution can change from image-to-image, case-to-case or patient-to-patient. Toker teaches providing a high contrast image in order to easily differentiate an object of interest from the background. Toker teaches that if the general characteristics of the object of interest and the background are known prior to acquisition of the image, an imaging signal detector for the particular object and background are automatically selected and used to enhance image quality. Toker teaches that the signal detection unit includes a carousel 28 which supports a number of signal detector elements 30 for

receiving a first imaging signal 13 and transmitting a second imaging signal 22 in response thereto. The signal detector elements 30 are described as being conventional phosphorescent screens which emit light upon excitation by X-ray radiation. (See Toker at Col. 5, lines 25-31).

Toker teaches that the carousel 26 supports more than one screen so that the illustrated lens-based digital imaging system can be adapted for specific imaging situations. Toker also teaches that selection of an appropriate screen is accomplished by prompting a controller to drive the carousel to a corresponding carousel position. Imaging feedback may be provided to give an indication of a deficiency in the image (e.g., that insufficient light has been received by the camera) which prompts the controller to select an imaging screen with a higher resolution.

In contrast to the disclosure of Toker, the present claimed invention is directed to a method for imaging anatomical parts of the human body based upon at least one initial projection image of a region of interest of the anatomy which has been acquired. The method also includes determining the positions and/or orientations of the anatomical parts in the region of interest.

Toker does not at all mention determining the positions and/or orientations of a plurality of anatomical parts in the region of interest from the at least one initial projection image so as to determine optimum imaging parameters for each of the plurality of anatomical parts. Toker instead determines a proper imaging screen to be used based upon whether there is sufficient contrast after a first initial image is acquired.

In view of the foregoing, claim 1 and claims 2-8 which are dependent thereon are patentable over Toker under 35 USC 102 as well as 35 USC 103.

Claim 9 is patentable over Toker for reasons, <u>inter alia</u>, set forth above in connection with claim 1.

NEW CLAIMS

New claim 10 is added to the present application. Claim 10 corresponds to the method recited in claim 1 but is specifically directed to imaging of the human spine. Claim 10 is patentable over the cited prior art for reasons, <u>inter alia</u>, set forth above in connection with claims 1 and 9.

It is respectfully believed that there is no additional fee due for the presentation of claim 10. However, if any additional

fees are due, please charge Deposit Account No. 14-1270 for such sum.

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If the Examiner disagrees with any of the foregoing, the Examiner is respectfully requested to point out where there is support for a contrary view.

Entry of the amendment, allowance of the claims, and the passing of the application to issue are respectfully solicited.

Respectfully submitted,

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COPY OF AMENDED CLAIMS SHOWING CHANGES BEING MADE THERETO SERIAL NO. 09/966,415

- 1. (Amended) A method for imaging <u>a plurality of</u> anatomical parts of the human anatomy by means of an X-ray apparatus, the method comprising the steps of:
- [-] acquiring at least one initial projection image of at least5 [the] a region of interest of the human anatomy,

determining the positions and/or orientations of the plurality of anatomical parts in the region of interest from the at least one initial projection image and/or from other sources of information,

determining optimum imaging parameters for each of the plurality of anatomical parts from their positions and/or orientations, and

acquiring images of the plurality of anatomical parts while

15 using respective optimum imaging parameters for each of the

plurality of anatomical parts.

2. (Amended) A method as claimed in claim 1,
[characterized in that the] wherein optimum exposure and/or

collimator settings are determined from the positions, orientations and/or appearance of the anatomical parts in the at least one initial projection image.

- 3. (Amended) A method as claimed in claim 1, [characterized in that the] wherein optimum projection lines for acquiring projection images of the anatomical parts are determined from the positions and/or orientations of the anatomical parts.
- 4. (Amended) A method as claimed in claim 1, [characterized in that] wherein the at least one initial projection image is taken as a frontal image and/or a lateral image.
- 5. (Amended) A method as claimed in claim 1, [characterized in that] wherein the at least one initial projection image is an overview image reconstructed from at least two projection images.
- 6. (Amended) A method as claimed in claim 1, [characterized in that] wherein an optimum projection line is determined for each anatomical part in the region of interest.

- 7. (Amended) A method as claimed in claim 1, [characterized in that] wherein the acquired images of the anatomical parts are displayed separately or are combined to form a composite image for display.
- 8. (Amended) A method as claimed in claim 1, [characterized in that] wherein the method is used for imaging the human spine and comprises the steps of:
- [-] acquiring at least one initial projection image of at least [the] <u>a</u> region of interest of the spine,
- [-] determining [the] positions and/or orientations of <u>each</u> of a plurality of vertebrae in the region of interest from the at least one initial projection image,
- [-] determining [the] optimum imaging parameters for each
 of the plurality of vertebrae from their positions and/or
 orientations, and
- [-] acquiring images of <u>each of</u> the <u>plurality of</u> vertebrae while using the optimum imaging parameters.
- 9. (Amended) An X-ray apparatus for imaging a plurality of [the] anatomical parts of the human anatomy, in particular parts of the human spine, having an x-ray source and an x-ray detector facing the x-ray source, the x-ray source and the x-ray detector

being movable with respect to each other and with respect to the patient so as to enable the acquisition of projection images of each of the plurality of anatomical parts from different positions and/or orientations, the x-ray apparatus comprising: $\lceil - \rceil$ a control unit for controlling the x-ray apparatus such that at least one initial projection image of at least [the] a region of interest of the human anatomy is acquired, and a processing unit for determining the position and/or orientation of anatomical parts in the region of interest from the at least one initial projection image and/or from other sources of information and for determining [the] optimum imaging parameters for each of the plurality of anatomical parts from their positions and/or orientations, the optimum imaging parameters being used by the control unit to control the x-ray apparatus such that images of each of the anatomical parts using the optimum imaging parameters are acquired.

Please add new claim 10 as follows:

--10. (New) A method for imaging the human spine comprising the steps of:

acquiring at least one initial projection image of at least a region of interest of the spine,

determining positions and/or orientations of vertebrae in the region of interest from the at least one initial projection image,

determining optimum imaging parameters for each of the vertebrae from their positions and/or orientations in the at least one initial projection image, and

acquiring images of each of the vertebrae while using the corresponding optimum imaging parameter for that vertebrae.--

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Method and X-ray apparatus for optimally imaging anatomical parts of the human anatomy

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The invention relates to a method for imaging the anatomical parts of the human anatomy by means of an X-ray apparatus as well as to an X-ray apparatus having an X-ray source and an X-ray detector facing the X-ray source, the X-ray source and the X-ray detector being movable with respect to each other and with respect to the patient so as to enable the acquisition of projection images of the anatomy from different positions and/or orientations.

Backround Inhoration
A method for imaging the human spine by means of a CT system is known from US 5,946,370. Therein two-dimensional data from CT scout images are combined with three-dimensional information from CT scans using simple modelling of vertebrae. It is often, however, preferred to image the spine of the patient in an upright position. A CT system cannot be used in such a case.

In digital X-ray imaging a composition of an image from sub-images is generally used to form a composite image of an elongate scene which is too long to be reproduced in one operation. In medical X-ray diagnostics such a situation occurs notably when an image of the spinal column is made. Using a contemporary digital X-ray examination apparatus it is difficult or even impossible to form an X-ray image of the complete region of the spinal column of the patient to be examined in one exposure. A number of successive X-ray images of portions of the region to be examined are formed, which images together cover the entire region. A method of this kind is also called the translation reconstruction technique and is known from EP 0 655 861 A1. Such a technique can also be used for imaging other parts of the human anatomy.

Due to the complexity of the scene (around the spinal column there are located other portions of the body like the thorax, rib cage, abdomen, head and neck which are also imaged when imaging the spine) and due to the mixture of over-projecting structures, projection images are often of low quality and limit the diagnostic reliability. Even when a normal-curved spine is imaged there are portions of the spine where neighbouring vertebrae

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may overlap each other in projection images. Furthermore, when the spine of a patient shows an abnormal curvature, e.g. an exagerated forward curvature (lordosis), an exagerated backward curvature (kyphosis) or a lateral curvature (scoliosis), such overlapping structures occur even more in the curved portions of the spine, thus reducing the quality of the projection images further. Another problem arises when the vertebrae of the spine exhibit an axial rotation. Consecutive projection images taken from the same direction will then show axially rotated vertebrae from different angles, thus reducing the diagnostic value of these images.

The translation reconstruction technique gives easy access to digital overview images of a large part of the human anatomy like the spine. Additionally, fluoroscopy can be used for optimum positioning of the patient and the collimators of the X-ray apparatus. However, much of the information contained in this fluoroscopy data currently is not used for the planning and optimizing of the real acquisition of images of the anatomical parts.

It is, therefore, an object of the invention to provide a method and an X-ray apparatus for imaging the anatomical parts that offer a better image quality and improve the diagnostic value and accuracy of the images.

This object is achieved according to the invention by a method as claimed in claim 1 and by an X-ray apparatus as claimed in claim 17.

It has been recognized according to the invention that information contained in at least one initial projection image can be used to reposition the X-ray apparatus automatically for subsequent optimum imaging of the region of interest of anatomical parts. This means that the information contained in the initial projection image is used to determine the optimum imaging parameters like position, direction, collimation or exposure parameters for the anatomical parts from their position and/or orientation in the initial image. Such determination of the optimum imaging parameters can be done for each single anatomical part or for groups of anatomical parts. Thereafter images of single parts or groups of parts can be acquired while using the optimum imaging parameters, and the images can be displayed separately, i.e. successively or side-by-side at the same time, or can be combined according to the translation reconstruction technique, thus forming a (curved) composite image, e. g. of the complete spinal column (if the acquisition trajectory allows so). In order to

[ABSTRACT:] ABSTRACT

anatomical parts of the human anatomy, in particular for imaging the human spine. In order to improve the quality and the diagnostic value of projection images of the anatomical parts (20) it is proposed according to the invention to acquire at least one initial projection image of at least the region of interest of the anatomy (20), to determine the positions and/or orientations of the anatomical parts in the region of interest from the at least one initial projection image and/or from other sources of information, to determine the optimum imaging parameters for the anatomical parts from their positions and/or orientations, and to acquire images of the anatomical parts while using the optimum imaging parameters. The complexity of the scene and the mixture of over-projecting structures limiting the diagnostic reliability of the projection images are thus taken into account. In a preferred embodiment a scanning trajectory (21) is determined while using the information of the at least one initial projection image along which the source-detector unit (1, 2) is moved while acquiring the projection images of the spine (20)

(Fig. 3)

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